

## **REMARKS**

### **1. Status**

Applicant respectfully requests favorable reconsideration of this application in light of the following remarks.

In the outstanding Final Office Action, claims 30-33 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the description requirement; claims 12-19, 21-23, and 26-29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Thiebault et al. (U.S. Patent Application Publication No. 2002/0121496 A1, "Thiebault"); claims 12, 13, 15, 19, 22, 24, and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Wadsworth, Jr. (U.S. Patent No. 5,374,264, "Wadsworth"); claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Thiebault in view of Meyer (U.S. Patent No. 5,358,501, "Meyer"); and claims 30-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Thiebault in view of Zinger et al. (U.S. Patent No. 6,238,372, "Zinger").

In this reply, Applicant amends claim 12 and 31; and adds claim 34. Claims 12-34 are thus currently pending. No new matter has been added.

### **2. Remarks on the § 112 Rejection**

Applicant respectfully requests favorable reconsideration of the rejection of claims 30-33 under 35 U.S.C. § 112, first paragraph, for the reasons set forth below.

The Office Action asserts at page 2 that "[t]he specification does not teach a free edge extending with a diameter greater than the rest of the edge portion away from the inward projection." Applicant respectfully disagrees. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that . . . applicant was in possession of the invention as now claimed [which can be shown]

by describing the claimed invention with all of its limitations using such descriptive means as . . . figures” (M.P.E.P § 2163.02). Here, while Applicant’s specification may not literally recite the features of claims 30-33 word-for-word, Figs. 1-9 all include an exemplary non-limiting inward projection (see, e.g., the inward projection near the bottom of distance A in Fig. 2), and an exemplary free edge clearly having a larger diameter than the rest of the edge portion away from the inward projection (see, e.g., the portion near 14 that flares outward, first obliquely and then axially, in Fig. 2).

Therefore, Applicant submits that the features of claims 30-33 satisfy the first paragraph of § 112 and respectfully requests favorable reconsideration of the rejection of claims 30-33 under § 112.

### **3. Remarks on the § 102(b) Rejections**

Applicant respectfully requests favorable reconsideration of the § 102(b) rejections based on Thiebault or Wadsworth for the reasons set forth below.

In the spirit of moving prosecution forward, Applicant amends independent claim 12 to recite “a sealing portion formed integrally with and extending from the lid portion, the sealing portion contacting the piercing portion,” and “wherein a distance between a base of the sealing portion and an end of the sealing portion on the piercing mandrel is less than a length between the base of the sealing portion and a lower surface of the elastic stopper within the container.” These features find non-limiting support at least in Figs. 2 and 5 of the originally-filed application. Applicant submits that neither Thiebault nor Wadsworth discloses these features.

The Office Action asserts at page 3 that Thiebault’s structures 52, 82, and 86 constitute sealing portions. Thiebault does disclose that the inner tubular portion 52 is

part of "a radial portions 48 which overlies and sealingly engages the rim portion 34" (paragraph [0024]). However, the inner tubular portion 52 does not contact Thiebault's piercing structures and is therefore not a "sealing portion contacting the piercing portion," as recited in claim 12.

Thiebault also discloses that "the flange 86 engages the abutment surface 53" (paragraph [0029]). However, even if "engages" were construed to mean "seals," *arguendo*, the "engaged" abutment surface 53 is a part of the transfer set 20 rather than the vial 22 (see Fig. 1) so that the flange 86 is not "configured to contact the *elastic stopper* when the bead is substantially disposed in the space," as recited in claim 12.

Finally, Thiebault also discloses that "[t]he piercing member 42 . . . includes a body portion 80 [and] a reduced diameter piercing portion 82" (paragraph [0026]). However, the reduced diameter piercing portion 82 is not "formed integrally with and extending from the lid portion" because the reduced diameter piercing portion 82 is a structure distinct from the cap 44 (asserted at page 3 of the Office Action to represent the "lid portion"). Moreover, the reduced diameter piercing portion 82 actually traverses the central portion 36, since it surrounds the channel 92 (see Fig. 1) and extends all the way to the tip 84. Therefore, Thiebault does not disclose that "a distance between a base of the sealing portion and an end of the sealing portion on the piercing mandrel is less than a length between the base of the sealing portion and a lower surface of the elastic stopper within the container," as recited in claim 12. Furthermore, because the reduced diameter piercing portion 82 is itself the piercing structure, it cannot also correspond to a sealing structure "having a diameter greater than a diameter of the piercing portion."

The Office Action further asserts at page 5 that Wadsworth's sheath 24 constitutes a sealing portion. Wadsworth does disclose that "[i]t can be seen that sheath 24 folds, accordi[o]n-like, as it is compressed between body portion 14 of the fitting and septum 45 on the culture bottle" (c. 4, ll. 25-27). Sheath 24, however, is not "formed integrally with and extending from the lid portion," as recited in claim 12, because it is a different structure than the body portion 14 to which is it attached (see Fig. 4).

For the foregoing reasons, Applicant submits that neither Thiebault nor Wadsworth discloses "a sealing portion formed integrally with and extending from the lid portion, the sealing portion contacting the piercing portion," and "wherein a distance between a base of the sealing portion and an end of the sealing portion on the piercing mandrel is less than a length between the base of the sealing portion and a lower surface of the elastic stopper within the container," as recited in amended independent claim 12. Accordingly, Applicant respectfully requests favorable reconsideration of the rejection of claims 12-19 and 21-29 as being anticipated by Thiebault or Wadsworth.

#### **4. Remarks on the § 103(a) Rejections**

In view of the above remarks, because neither Meyer nor Zinger discloses the aforementioned features of amended independent claim 12 not taught by Thiebault or Wadsworth, Applicant respectfully request favorable reconsideration of the § 103(a) rejections of claims 20 and 30-33 as being unpatentable over Thiebault in view of Meyer or Zinger.

In addition, Applicant amends dependent claim 31 to distinguish even further over the prior art by reciting that the free edge extends away from the inward projection

“at least partly along a direction substantially parallel to a central longitudinal axis of the receiving cap.”

#### **5. New Claim**

Applicant adds new independent claim 34 to vary the scope of protection recited in the claims. Claim 34 finds non-limiting support at least in Figs. 2 and 5 of the originally-filed application. Applicant submits that the prior art does not disclose all the features of claim 34.

#### **6. Concluding Remarks**

Applicant respectfully requests that this Amendment After Final under 37 C.F.R. § 1.116 be entered. Applicant respectfully points out that the Final Office Action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the outstanding rejections and place the application in condition for allowance. Finally, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

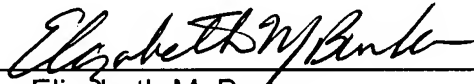
In view of the foregoing remarks, Applicant submits that the pending claims are neither anticipated nor rendered obvious in view of the cited prior art. Applicant therefore requests the entry of this Amendment, favorable reconsideration of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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